RECORD AND BRIEFS

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IN THE

Supreme Court of the United States

IMPRESSION PRODUCTS, INC.,

Petitioner,

v.

LEXMARK INTERNATIONAL, INC.,

Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF AMICUS CURIAE PUBLIC CITIZEN, INC., IN SUPPORT OF PETITIONER

SCOTT L. NELSON
Counsel of Record
ALLISON M. ZIEVE
PUBLIC CITIZEN LITIGATION GROUP
1600 20th Street NW
Washington, DC 20009
(202) 588-1000
snelson@citizen.org
Attorneys for Amicus Curiae

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INTEREST OF AMICUS CURIAE[1]

Founded in 1971, amicus curiae Public Citizen, Inc., is a nonprofit consumer advocacy organization with members and supporters nationwide. Public Citizen appears before Congress, administrative agencies, and courts on a wide range of issues, including access to affordable medicines for consumers both domestically and globally. Through its Access to Medicines program, Public Citizen works with partners worldwide to improve health outcomes and save lives by advancing policies to lower pharmaceutical prices. Public Citizen has provided technical assistance concerning patent rules and access to medicines to dozens of governments as well as to international organizations. Public Citizen is particularly concerned with increasing access to medicines in countries where incomes are lower than in the United States and other highly developed countries.

Public Citizen submits this brief to address assertions made below that the rule of international patent exhaustion advocated by petitioner Impression Products, Inc., would impair access to affordable medicines in low- and middle-income countries. Those arguments were advanced in the court of appeals by the Pharmaceutical Research and Manufacturers of America (PhRMA) in an amicus curiae brief supporting Lexmark, Inc., and advocating that the Federal Circuit adhere to its decision in *Jazz Photo Corp. v. ITC*, 264 F.3d 1094 (Fed. Cir. 2001), notwithstanding this Court's intervening decision in

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[1] This brief was not authored in whole or part by counsel for a party. No one other than amicus curiae made a monetary contribution to preparation or submission of this brief. Written consents to its filing from counsel for both parties are on file with the Clerk.

Kirtsaeng v. John Wiley & Sons, Inc., 133 S. Ct. 1351 (2012).[2]

Public Citizen does not believe that patent-law doctrines that affect all forms of technology should be driven by concerns specific to a particular industry. Nor does Public Citizen believe that limiting exhaustion of patent rights to domestic sales is an appropriate or effective way to protect the critically important interest in access to affordable medications in other countries. Indeed, domestic exhaustion requirements, particularly if they were to be adopted worldwide, are likely to hinder that goal. Public Citizen submits this brief to explain that, to whatever extent the Court may view access-to-medicines issues as relevant to its decision in this case, PhRMA's policy arguments on the subject do not reflect the views of advocates for global access to medicines.

INTRODUCTION AND SUMMARY OF ARGUMENT

The brief of petitioner Impression Products, Inc., and those filed by other amici curiae on its behalf explain how the Federal Circuit's precedents allowing the use of patent law to enforce conditions on the sale of patented products and limiting the principle of patent exhaustion to first sales of patented products in the United States run counter to decades of this Court's patent-law precedents, to the common-law principles animating them, and to sound public policy. This brief will not repeat those arguments. Instead, this brief addresses a specific argument made by representatives of the pharmaceutical industry in support of the Federal Circuit's holding that

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[2] *See* Br. of Amicus Curiae Pharma. Research & Mfrs. of Am., *Lexmark Int'l, Inc. v. Impression Prods, Inc.*, Nos. 14-1617 & 14-1619 (Fed. Cir. filed Aug. 19. 2015) ("PhRMA App. Br.").

foreign sales authorized by U.S. patent holders do not exhaust U.S. patent rights. That argument is that a rule of international exhaustion would harm access to medicines in lower-income countries by allowing parallel importation to the United States of patented drugs sold at lower prices, and sometimes donated free of charge, in those markets. Such importation, the industry argues, would diminish the incentive for pharmaceutical companies to offer drugs at reduced prices in other countries and ultimately drive prices up, denying life-saving medicines to patients in the developing world. The argument is both misdirected and misguided.

The argument is misdirected because concerns specific to a single industry should not drive the development of patent-law principles that govern rights of patent-holders across all industries: Manufacturers of printer cartridges need not be given property rights to prevent distortion of markets for medicine. Concerns specific to parallel importation of pharmaceuticals are best addressed—and already addressed—by legislation specific to that subject.

The argument is misguided because it wrongly suggests that access to medicine is an interest best protected by pharmaceutical monopolists. In fact, pricing by pharmaceutical patent-holders has been an obstacle to affordable access to medicine in lower- and middle-income countries. Indeed, despite regulatory policies in the United States and other higher-income countries that effectively prevent parallel importation of drugs sold at lower prices in lower-income countries, millions of lives were lost to HIV/AIDS in such countries because of the resistance of the pharmaceutical industry to providing life-saving medicines at affordable prices until public policies and the pressure of world opinion led to price re-

ductions. Parallel importation was one means successfully used to help lower prices in those markets.

Thus, although mass-scale, commercial parallel importation to the United States of medicines sold at low prices in lower-income countries could, if permitted, have negative consequences, not all parallel importation of pharmaceuticals would have such effects. Indeed, parallel importation is a critical tool that developing countries have used to combat excessive prices charged by drug companies with patent monopolies, and to save many lives. Targeted regulatory and trade policies, not broad grants of rights to patent-holders, present the best options for facilitating access to medicines worldwide.

ARGUMENT

I. General patent-law rules should not be based on policy concerns specific to the pharmaceutical industry and already addressed by legislation regulating that industry.

The products at issue in this case are computer printer-ink cartridges, but the issues posed by the case are not limited to those products. The impact of the Court's holding will be felt across a wide range of industries whose products use patented technologies. Any product subject to a U.S. patent that is sold abroad with the patentee's authorization and then brought into this country, whether for resale or for use by the original purchaser, will be affected by the Court's ruling.

Because the patent-law principles the Court must address—and in particular the issue of international patent exhaustion—are not specific to any one industry, technology, or set of products, policy concerns limited to the impact of a ruling on any single market seem poorly suited to drive the Court's decision. Effects limited to one set of manufacturers, or the consumers of their products,

would not ordinarily justify extending monopoly rights of *all* patent holders beyond the first authorized sale abroad.

The price of medicines in developing countries is an extraordinarily serious issue—literally a matter of life and death. Patent-law principles of general effect, however, are particularly blunt instruments, at best, for attempts to achieve policy aims specific to drug pricing in lower- and middle-income countries.

PhRMA has argued, for example, that large-scale reimportation of medicines marketed abroad at reduced prices (whether for humanitarian reasons or based on the operation of market forces in foreign countries) would increase prices and reduce availability of drugs in those countries (either by reducing companies' willingness to engage in below-market pricing or by increasing demand and thus raising market prices). PhRMA App. Br. 24–28. Even if that is the case, legislation and trade policies directed specifically at drug reimportation are a far more calibrated policy response than the blunderbuss approach of granting all patent-holders the right to sell products abroad without exhausting patent rights.

Indeed, laws specifically addressing and limiting parallel imports of medicines already exist. In particular, 21 U.S.C. § 381(d)(1), enacted in 1988, generally bars anyone other than the manufacturer from reimporting drugs manufactured in this country and sold abroad. That legislation effectively prevents large-scale parallel importation of drugs originating in the United States and thus renders the impacts predicted by PhRMA unlikely.[3]

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[3] Section 381(d)(1) does not address importation by overseas purchasers of drugs manufactured *abroad* by U.S. patent-holders. However, even under the rule that an authorized purchase of such

(*Footnote continued*)

In the court of appeals, PhRMA argued that this existing prohibition on reimportation is inadequate to meet its professed policy concerns because it is "addressed to safety rather than patent concerns." PhRMA App. Br. 28. But although the law's motivation may have been safety concerns (specifically, concerns about the potency and possible adulteration of reimported drugs), its prohibition is not limited to circumstances in which reimported drugs are unsafe. Whatever its original intent, its effect is, at a minimum, to limit significantly the possibility that parallel imports to the United States will affect prices in overseas markets.[4]

PhRMA also argued below that 21 U.S.C. § 381(d)(1) "does not supplant or alter patent rights" and thus does not "take away" patentees' rights to sue for patent damages for reimportation. PhRMA App. Br. 28. That argument begs the question in a case where the issue is whether such patent rights exist. PhRMA has offered a policy argument for holding that patent rights are not exhausted by foreign sales, and the existence of alternate statutory means for achieving those policies is an answer

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drugs abroad exhausts the patentee's U.S. patent rights, large-scale commercial importation of those drugs without the cooperation of the manufacturer would face great legal obstacles because, to be sold in the United States, the drugs would have to be packaged and labeled in conformity with FDA requirements, and the importer would have to demonstrate compliance by the manufacturer with all requirements applicable to the production of drugs for sale in the United States. *See* 21 U.S.C. § 381(a).

[4] *See* Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 Yale J. Health Pol'y L. & Ethics 193, 213–14 (2005) ("The law was ostensibly intended to address safety concerns for the U.S. pharmaceutical supply chain, but its effect is to prevent international pharmaceutical arbitrage or parallel trade.").

to that argument. Thus, our position is not that "patentees should be forced to rely on the FDA to protect their private rights" by enforcing 21 U.S.C. § 381(d)(1). PhRMA App. Br. 28. It is that patentees' "private rights" are exhausted by first sales abroad, and that legislation and policies specifically aimed at trade in medicines are a more tailored means of responding to policy concerns about drug reimportation than expanding the "private rights" of all patentees by holding that those rights are not exhausted by foreign sales.

Moreover, limiting patent exhaustion to domestic sales would strike a very different balance with respect to parallel drug imports than the one Congress chose in enacting § 381(d). Section 381(d)(2), for example, allows reimportation by persons other than manufacturers if the Secretary of Health and Human Services authorizes such reimportation because "the drug is required for emergency medical care." Section 381(d)(1) also has an exception for reimportation permitted under 21 U.S.C. § 384, a provision adopted in 2003 to authorize the Secretary to promulgate regulations permitting importation of drugs from Canada by persons other than manufacturers, although no such regulations have yet been promulgated.[5] A rule limiting patent exhaustion to domestic first sales would potentially prevent importation of patented drugs that could otherwise be authorized by the Secretary under these authorities.

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[5] Notably, to prevent any possible diversion of medicines donated for humanitarian reasons, § 384 prohibits the Secretary from allowing imports of "a prescription drug that is donated or otherwise supplied at no charge by the manufacturer of the drug to a charitable or humanitarian organization (including the United Nations and affiliates) or to a government of a foreign country." 21 U.S.C. § 384(i).

Whether existing laws and their regulatory implementation strike the correct balance with respect to parallel importation is subject to debate. But for purposes of this case, the relevant points are twofold: First, issues concerning the effects of drug importation policies on access to medicines domestically and internationally are best addressed in laws and regulations specifically applicable to drugs rather than in generally applicable patent-law principles. Second, existing laws make it very unlikely that recognizing that authorized sales abroad exhaust U.S. patent rights would lead to a volume of parallel importation from low-income countries that would affect drug markets and access to medicine in those countries.

II. Blanket bans on international exhaustion and parallel importation of pharmaceuticals would worsen problems of access to medicine in developing countries and likely cost lives.

The contention that the principle of international exhaustion of patent rights, and the resulting potential for parallel importation of patented drugs, is necessarily harmful to access to medicines in low-income countries is, in any event, overly simplistic and inaccurate. The argument rests on the premise that, if parallel importation is prohibited, pharmaceutical patent-holders will set an appropriate, affordable price for their products in each country, which would be disrupted if consumers in wealthier nations were able to compete with consumers in lower-income countries for lower-priced drugs available there.

That premise is at odds with reality. Drug prices certainly vary greatly from country to country, but not necessarily in ways that correspond to relative levels of in-

come or economic development.[6] Pharmaceutical companies with patent protection for their products tend to limit supply and set prices in each market to maximize monopoly profits; it would be surprising if monopoly pricing tended to produce results optimal for promoting wide access to medicines at affordable prices.[7]

Rather, economic theory suggests that income inequality in poorer countries produces demand curves for medicine that enable "a monopolist [to] maximize its revenue by selling at a high price affordable to few people," and thus "it may be perfectly rational for a company to set very similar prices in rich and poor countries."[8] Empirical evidence bears out that prices for patented drugs in poorer countries are often not significantly lower than in wealthier countries, and they may be higher.[9] For example, before generic versions of antiretroviral drugs became available, antiretroviral drug prices "had little or no relationship to developing countries' per-capita incomes."[10]

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[6] *See* Keith Maskus, *Parallel Imports in Pharmaceuticals: Implications for Competition and Prices in Developing Countries*, World Intellectual Property Organization, at 28–31 (April 2001), http://193.5.93.81/export/sites/www/about-ip/en/studies/pdf/ssa_maskus_pi.pdf.

[7] *See* Outterson, *supra* note 4, at 227.

[8] Sean Flynn, *et al.*, *An Economic Justification for Open Access to Essential Medicine Patents in Developing Countries*, 37 J.L. Med. & Ethics 184, 190 (2009)

[9] *See id.* & nn. 41–42.

[10] Rebecca Hellerstein, *Do Pharmaceutical Firms Price Discriminate Across Rich and Poor Countries? Evidence from Antiretroviral Drug Prices* (Aug. 2004), http://s3.amazonaws.com/zanran_storage/www.ny.frb.org/ContentPages/152635400.pdf.

Far from advancing access to medicines in developing countries, the pricing practices of patent monopolists have been a significant obstacle to making drugs affordable to citizens of those countries, where life-saving medicines often are in limited supply at prices beyond the reach of much of the population.[11] Strategies for reducing drug prices in poor and middle-income countries have often met significant resistance from patent-holders.[12] Those strategies have included fostering generic competition, including through compulsory licensing; price controls; and public and political pressure on the pharmaceutical industry.[13] Of particular relevance here, some lower-income countries, including South Africa, have significantly lowered prices and expanded access to life-saving medicines, including HIV drugs, by adopting the principle of international patent exhaustion and encouraging parallel importation from other countries where prices are lower.[14]

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[11] Ellen t'Hoen, *TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha*, 3 Chi. J. Int'l L. 27, 27 (2002).

[12] *See generally* Peter Yu, *The International Enclosure Movement*, 82 Ind. L.J. 827 (2007).

[13] *See generally* World Health Organization, *Managing Access to Medicines and Health Technologies, Chapter 3: Intellectual Property and Access to Medicines* (2012), http://apps.who.int/medicinedocs/documents/s19580en/s19580en.pdf; United Nations Development Program, *Using TRIPS Flexibilities to Improve Access to HIV Treatment*, http://www.undp.org/content/dam/undp/library/hivaids/Using%20TRIPS%20Flexibility%20to%20improve%20access%20to%20HIV%20treatment.pdf.

[14] *See* Sisule Musungu, *et al.*, *The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines?*, World Health Organization, Commission on Intellectual Property Rights, Innovation and Public Health, at 28–30 (Aug. 2005), http://

(*Footnote continued*)

Notably, even when lower-income countries such as South Africa have sought to use parallel importation to bring about lower prices for essential medicines, pharmaceutical companies have opposed it on the same grounds they invoked in this case: "'parallel importation of drugs would undermine the ability of pharmaceutical companies to charge different prices in different parts of the world,' and ... 'tiered pricing strategy allows wealthier countries to subsidize poorer ones, so the drug companies still get profits they need for research.'"[15] Actual experience suggests that, on the contrary, "[p]arallel importing can be an important tool enabling access to affordable medicines because there are substantial price differences for pharmaceutical products in different markets."[16]

The use of patent exhaustion and parallel importation to advance access to medicines in some developing countries suggests that the broad-brush assertion that rejection of international exhaustion is necessary to protect affordable access to medicines in the developing world is overstated. A more nuanced approach to the subject would recognize that the advantages and disadvantages of parallel importation depend on the circumstances.

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www.who.int/intellectualproperty/studies/TRIPSFLEXI.pdf; William Fisher *et al.*, *The South Africa AIDS Controversy: A Case Study in Patent Law and Policy* (Feb. 2005), https://cyber.harvard.edu/people/tfisher/South%20Africa.pdf.

[15] Fisher, *supra* note 14, at 6 (citation omitted).

[16] Musungu, *supra* note 14, at 30. *See also* Maskus, *supra* note 6, at 10 ("[I]t seems from available price evidence that prices are often higher ... in developing nations than would be expected under a simple price-discrimination equilibrium and, indeed, are at times higher than in the rich nations. Under such circumstances [parallel importation] can provide a welcome source of lower-cost drugs.").

Parallel importation between countries with comparable levels of income but significant disparities in drug prices may help equalize prices and help consumers in the higher-priced market to access medicine, without pricing large numbers of consumers in the exporting country out of the market, threatening public health, or depriving patent holders of returns sufficient to incentivize innovation.[17] The flat rejection of international exhaustion advocated by PhRMA and Lexmark would prevent such potentially beneficial transactions (assuming they were otherwise permissible under the regulatory and trade policies of the countries involved). As one economist has concluded, "[a] more sensible conclusion is that parallel trade could be beneficial among countries with similar demand structures."[18]

We recognize that, in circumstances where lower-income nations have succeeded in overcoming the resistance of patent-holders and bringing about the lower prices for patented medicines that are essential to facilitating broader public access in those countries, mass-scale commercial parallel importation to the United States from those countries could have negative consequences. As explained above, however, existing regulatory obstacles to parallel importation to this country are likely to prevent such consequences. Indeed, "rules prohibiting importation of preferentially-priced medicines are already in place in almost all of the developed countries."[19]

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[17] *See* Outterson, *supra* note 4, at 197; Keith Maskus, *et al.*, *The Price Impact of Parallel Imports in Pharmaceuticals: Evidence from the European Union*, 23 J. Health Econ. 1035 (2004).

[18] Maskus, *supra* note 6, at 20.

[19] Musungu, *supra* note 14, at 30.

Moreover, even if regulatory policies allowed such importation, adoption of the principle that only domestic sales exhaust patent rights would be an overly broad solution to the potential problem because it would prevent parallel imports even where adverse consequences were not likely.[20] A preferable solution would be selective regulatory or trade policies, where appropriate, "to exclude drugs first sold in least developed countries."[21]

In the end, pharmaceutical interests concerned with the protection of monopoly profits are unlikely and uncertain protectors of the interest in affordable global access to medicines. Although protection of affordable drug prices in the developing world is a matter of critical importance, the proper mechanism for achieving that end is not a principle of patent exhaustion that protects the ability of all patent-holders in all industries to maximize their monopoly rents in every country where they do business, but policies specifically addressing the complex issues of global access to medicines.

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[20] Moreover, to the extent lower prices in a lower-income country were attributable to generic competition or a compulsory licensing system, a rule of international exhaustion would not permit parallel importation of lower priced generics even in the absence of regulatory constraints. Sales of those products in the lower-income country would not exhaust the patent-holders' U.S. patent rights because they would not be sales authorized by the patent-holder. *See* Sarah Wasserman Rajec, *Free Trade in Patented Goods: International Exhaustion for Patents*, 29 Berkeley Tech. L.J. 317, 373 (2014).

[21] Rajec, *supra* note 20, at 373; *see also* Maskus, *supra* note 6, at 43 & Annex A (advocating prohibiting parallel trade in pharmaceuticals offered at below-market prices in low-income countries).

CONCLUSION

This Court should reverse the judgment of the court of appeals.

Respectfully submitted,

SCOTT L. NELSON
Counsel of Record
ALLISON M. ZIEVE
PUBLIC CITIZEN LITIGATION GROUP
1600 20th Street NW
Washington, DC 20009
(202) 588-1000
snelson@citizen.org
Attorneys for Amicus Curiae

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